

HONORABLE BARBARA J. ROTHSTEIN



MDL 01 01407 000000676

FILED
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MR
CLERK U.S. DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
DEPUTY

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

IN RE Phenylpropanolamine (PPA) Products)
Liability Litigation)

No. MDL 1407

-----)
This document relates to all actions.)

STIPULATION FOR ISSUANCE OF
LETTERS ROGATORY

It is hereby stipulated by and between the parties by their respective counsel, that Letters Rogatory of the form attached hereto may be issued by the United States District Court for the Western District of Washington to the appropriate Judicial Authority in Canada in the above-captioned case.

DATED this 28 day of June, 2002.

LANE POWELL SPEARS LUBERSKY LLP

By D. Joseph Hurson
D. Joseph Hurson
WSBA No. 09296
Co-Liaison Counsel for the PPA
Manufacturer-Defendants

STIPULATION FOR ISSUANCE OF LETTERS
ROGATORY - 1

Case No. MDL 1407

019186.0028:932349.1

LANE POWELL SPEARS LUBERSKY LLP
SUITE 4100
1420 FIFTH AVENUE
SEATTLE, WA 98101
(206) 223-7000

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1 LEVINSON FRIEDMAN P.C.

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3 By 

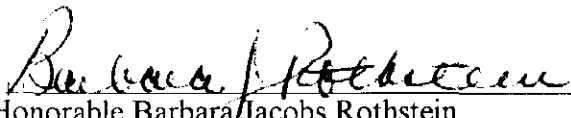
4 Lance E. Palmer

5 WSBA No. 18141

6 Plaintiffs' Liaison Counsel

7 IT IS SO ORDERED:

8 DATED: June 28, 2002

9 
10 Honorable Barbara Jacobs Rothstein

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STIPULATION FOR ISSUANCE OF LETTERS

ROGATORY - 2

Case No. MDL 1407

019186.0028/932349.1

LANE POWELL SPEARS LUBERSKY LLP

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1 HONORABLE BARBARA J. ROTHSTEIN

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7 UNITED STATES DISTRICT COURT
8 WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

9 IN RE Phenylpropanolamine (PPA) Products) No. MDL 1407
10 Liability Litigation)
11 -----)
12 This document relates to all actions.) LETTERS ROGATORY
13 -----)

14 THE UNITED STATES DISTRICT COURT OF THE WESTERN DISTRICT OF
15 WASHINGTON TO THE APPROPRIATE JUDICIAL AUTHORITY IN CANADA:

16 WHEREAS, the Multi-District Litigation Panel has ordered all federal cases filed
17 across the United States transferred and consolidated into MDL No. 1407 in the Western
18 District of Washington for purposes of pretrial matters, Defendants believe that the testimony
19 of Samy Suissa, whose work address is Royal Victoria Hospital, 1020 Pine Avenue West,
20 Montreal, Quebec, Canada H3A 1A2, within your jurisdiction, and documents in his
21 possession would aid in the proof of the invalidity of Plaintiffs' claims.

22 WE THEREFORE REQUEST, that in the interest of justice, you issue an order by
23 your proper and usual process summoning Samy Suissa to appear before a duly appointed
24 official in Canada, with all documents requested (identified in the attached Exhibit A), at an
25 appropriate time and place, to give testimony under oath by question and answers upon oral
26 deposition, such deposition to continue from day-to-day until completion.

LETTERS ROGATORY - 1
Case No. MDL 1407
019186.0028/932350.1

LANE POWELL SPEARS LUBERSKY LLP
SUITE 4100
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SEATTLE, WA 98101
(206) 223-7000

1 IT IS FURTHER REQUESTED that you cause these depositions to be reduced to
2 writing, and cause said depositions, with all exhibits marked and attested, to be returned to us,
3 through the nearest United States consular officer under cover, duly sealed and addressed to
4 the Clerk of the United States District Court for the Western District of Washington, the
5 United States of America, and we shall be ready and willing to do the same thing for you in a
6 similar case, when required.

7 Witnesseth, Honorable Barbara Jacobs Rothstein, Judge of the United States District
8 Court for the Western District of Washington, the 28th day of June, 2002, at Seattle,
9 Washington.

BRUCE RIFKIN

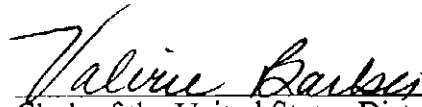
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11 Clerk of the United States District Court
12 for the Western District of Washington
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EXHIBIT "A"

As used herein, the term "document" or "documents" shall mean and include any written, printed, drawn, recorded, transcribed, filed or graphic matter, however produced, reproduced, or stored on computer or otherwise electronically stored, and any originals, copies, drafts, revisions, or amendments thereof. "Document" or "Documents" shall include, by way of example and without limitation, letters, memoranda, notes, e-mails, test data, charts, x-rays, reports, medical records, records of payment, diagrams, manuals, test procedures, sketches, graphs, prints, secretarial notes, work pads, diaries, films, tapes, videotapes, photographs, computer disks, computer printouts, computer memory banks, books, publications, literature, announcements, or other writings or tangible objects. Further, "document" or "documents" requested herein extend to and include any and all such materials within the possession, custody, or control of you and your agents, attorneys, or representatives, regardless of where located. For any document withheld from production, and any document redacted in any manner, please identify the document withheld or redacted by date, author, type of document, subject matter, recipient, and any grounds for withholding or redaction of the document. You are to produce the materials in your possession, custody, or control listed below:

1. All documents related to the initiation of the Yale Hemorrhagic Stroke Project (hereinafter "HSP").
2. All documents related to the organizational structure of persons involved in the HSP.
3. All documents relating to the study personnel's experience and credentials (including but not limited to the curriculum vitae of each professional who participated in the study).
4. All medical literature and case reports that were considered, reviewed, relied upon, and/or utilized in any manner by you or by any investigator or other personnel involved in the HSP from the inception of the HSP until its publication in the New England Journal of Medicine.
5. All documents related to the Protocol for the HSP including, but not limited to:
 - a) all documents related to the creation or development of the Protocol;
 - b) all documents related to the estimation of the sample size, including MRI market research data;
 - c) all documents related to or containing communications with anyone regarding the Protocol;

- d) all documents related to comments, revisions, or modifications to the Protocol; and
 - e) all drafts of the protocol.
- 6. All documents related to obtaining Institutional Review Board Approval of the HSP.
- 7. All documents related to the conduct of the HSP including, but not limited to:
 - a) all documents regarding or concerning the network of participating hospitals;
 - b) all documents regarding the recruitment of investigators, hospitals, and all persons involved in any way in the HSP;
 - c) all procedure manuals and all investigator's brochures; and
 - d) all documents regarding the training of any and all persons involved in the HSP, including but not limited to training manuals, training videotapes, training attendance, identity of trainers, and confirmation of training.
- 8. All documents related to the ascertainment of cases in the HSP including, but not limited to, all documents regarding:
 - a) the active surveillance program;
 - b) the surveillance team;
 - c) the case definition;
 - d) methods of case ascertainment; and
 - e) exclusion criteria.
- 9. All documents related to the selection of controls in the HSP including, but not limited to, all documents regarding the use of random digit dialing and all documents concerning telephone numbers that did not result in an eligible person or control.
- 10. All documents related to data collection and processing in the HSP including, but not limited to:
 - a) all data collection forms;

- b) all interview data forms;
- c) training manuals for interviewers;
- d) data logs regarding cases and controls;
- e) all case identification forms;
- f) all potential control forms;
- g) all log-in records;
- h) all data editing, coding and validation manuals;
- i) all screening questionnaires;
- j) all documents and records reviewed by a panel of stroke neurologists involved in the determination of whether eligibility criteria were met;
- k) all documents and records reviewed or generated by study physicians;
- l) all documents and records, including logs, regarding stroke patients rejected as not meeting eligibility criteria;
- m) all medical records and scans (e.g., CT, MRI, MRA, angiogram, etc.);
- n) all documents regarding scheduling of interviews and collection of information from all study participants;
- o) all product identification books, photographs, and charts;
- p) all drug containers and drug labels furnished by study participants;
- q) all documents related to observations of interviews;
- r) all documents related to the assignment of interviewers;
- s) all documents related to surrogate/proxy interviews;
- t) all documents related to the use or handling of data or information obtained from surrogate/proxy interviews;

- u) all data abstraction forms;
 - v) all coding forms;
 - w) all documents related to codes, including their definition;
 - x) all documents relating to the monitoring of sample size;
 - y) all documents related to modification of any aspect of the HSP;
 - z) every participating subject's folder and all contents of the folder;
 - aa) all audio tapes of interviews of study subjects;
 - bb) all financial reports; and
 - cc) all documents regarding the disbursement of funds.
11. All documents regarding the proxy respondent sub-study.
 12. All documents regarding communications concerning the HSP including, but not limited to, all documents regarding communications:
 - a) between persons participating in the conduct of the HSP. (For purposes of this Item 12, "conduct" is defined to including without limitation the design of the HSP, analysis of data, variations of or amendments to the HSP protocol variations, and the drafting or revision of abstracts, summaries, manuscripts and/or submissions relating to the HSP);
 - b) between anyone involved in the conduct of the HSP and any other person or organization including, but not limited to, yourself, the Food and Drug Administration, the Nonprescription Drug Manufacturers Association, the Consumer Healthcare Products Association, any other member of the Scientific Advisory Group, pharmaceutical companies, and/or any of their current or former employees, members or representatives;
 - c) between anyone involved in the conduct of the HSP and any person claiming injury from use of PPA-containing medication;
 - d) with physician investigators;

- e) with participating hospitals including, but not limited to, communications with the surveillance officers and the admissions offices at the participating hospitals;
 - f) with the Principal Investigator at each participating study site;
 - g) with each case's physician;
 - h) with any medical or scientific journals including, without limitation, the New England Journal of Medicine;
 - i) with any physicians, epidemiologists, statisticians, or other professionals asked by any person or entity (including, but not limited to, the New England Journal of Medicine) to conduct a peer review of the study and its results;
 - j) between HSP investigators and you or any other member of the Scientific Advisory Group;
 - k) between HSP investigators and the New England Journal of Medicine; and
 - l) with any other person at any of the participating institutions.
13. All documents related to your participation in the Scientific Advisory Group including, but not limited to, communications, reports, site visits, and travel expenses.
14. All documents regarding the handling, calculations, or use of any and all data obtained regarding the HSP including, but not limited to:
- a) all electronic analysis files;
 - b) all documents related to interim data analysis;
 - c) all final analysis files; and
 - d) all data access logs;
 - e) all database dictionary files;
 - f) all data collection instruments;
 - g) all databases constructed from the questionnaires;

- h) all databases for each intermediate and final analysis that relates to the Final Report and the New England Journal of Medicine article;
 - i) all analyses not included in the Final Report or the New England Journal of Medicine Article;
 - j) all analyses done after receipt of comments from or on behalf of CHPA or any predecessor organization of CHPA;
 - k) all documents concerning the use of and/or difference between data analysis via a one-tailed or two-tailed statistical test;
 - l) all documents concerning the adjustment of variables and analyses used for the adjustment of variables.
- 15. All documents regarding the Final Report of the HSP and its preparation including, but not limited to, all communications, comments and drafts.
 - 16. All documents regarding the publication of the HSP in the New England Journal of Medicine, including but not limited to correspondence dated after publication of the HSP in the New England Journal of Medicine.
 - 17. All documents evidencing revisions, changes, additions, or deletions made to the Final Report of the HSP (and/or the data contained in that report) prior to the publication of the study's results in the New England Journal of Medicine.
 - 18. All documents regarding conferences, discussions, or meetings with FDA regarding the HSP, including, without limitation, documents concerning preparations for October 19, 2000 hearing.
 - 19. All documents relating to any comments about, or criticisms of, The HSP from any source including, without limitations, letters to the editor concerning the HSP.
 - 20. All documents regarding the Authors' Reply published in the April 5, 2001 New England Journal of Medicine including, but not limited to, all data analyses and communications with anyone after publication.
 - 21. All documents relating to the removal or refiling of any document responsive to any of the above categories.